

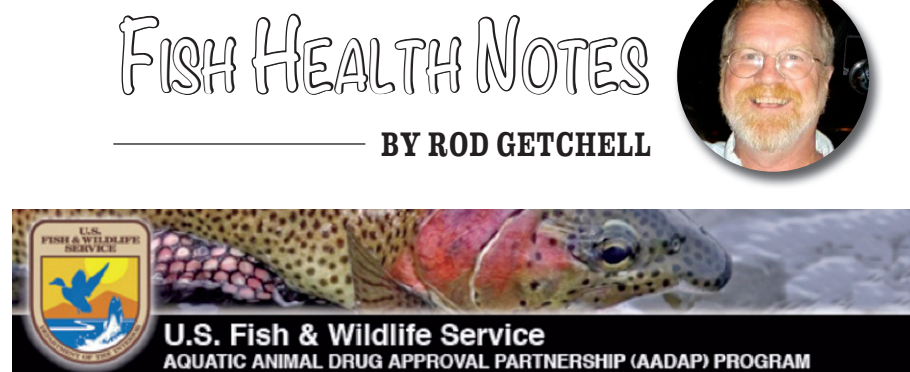
Updated drug guide can steer fish farmers away from trouble

BOZEMAN, MT – In the last issue of *Fish Farming News*, I focused on the Fish Health Section Blue Book, which I described as the virtual bible of the fish health world. This time, I'm going to discuss an equally important publication from the Fish Culture Section of the American Fisheries Society – the 2014 update of the "Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture."

Every fish farmer should be aware of this guide, which explains the proper use of drugs, biologics, and other chemicals and describes regulated products that are approved for use in US aquaculture.

The guide also outlines drugs not yet approved for use in the US that can be used under an Investigational New Animal Drug (INAD) exemption and additionally lists drugs that are considered to be of low regulatory priority enforcement.

The Fish Culture Section established a Working Group on Aquaculture Drugs, Chemicals, and Biologics to develop the guide by facilitating communication and cooperation between public and private aquaculture interests, academic and agency researchers, and regulators. All of those involved are addressing the needs and issues associated with the approval



and use of aquatic animal drugs, biologics, and other regulated products in aquaculture.

In previous columns, I've mentioned the limited number of disease treatment options available to fish farmers and stressed that improper use of products can get you into trouble with the regulatory authorities or, more importantly, create pathogens resistant to the very treatments you depend on.

The guide can help steer you down the right treatment path. Just remember that it's not meant to be a prescriptive tool or to replace advice provided by professional fish health biologists or licensed veterinarians.

Regulated products?

Aquaculture operations need products such as: disinfectants as part of biosecurity protocols; herbicides and pesticides used in pond maintenance; spawning aids; vaccines used in disease prevention; marking agents used in resource management; and, despite the best efforts of fish culturists to avoid pathogen introductions, therapeutic drugs to occasionally control mortality, infestations, or infections.

The US Fish and Wildlife Service's Aquatic Animal Drug Approval Partnership (AADAP) conducts real-life field investigations and consolidate data generated from over 130 entities

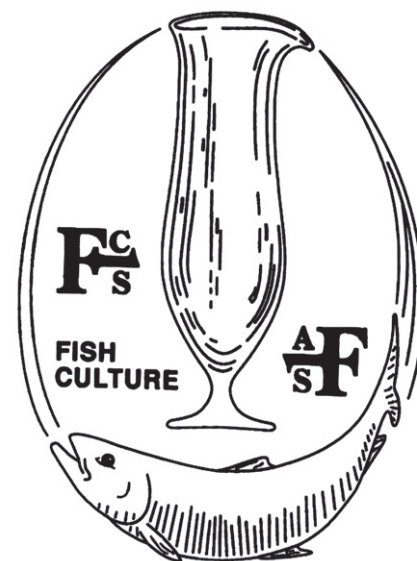
comprised of state and federal agencies, Native American tribes, and private companies, all striving to get new aquatic animal drugs approved.

These scientists spend years ensuring that culturists have access to products that are safe and effective. So, fish farmers should apply them in a manner that is consistent with their intended use, best management practices, and relevant rules and regulations.

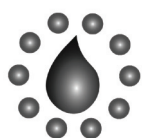
Sections

The drug section of the guide covers the various types of approved drugs and their uses and also describes some

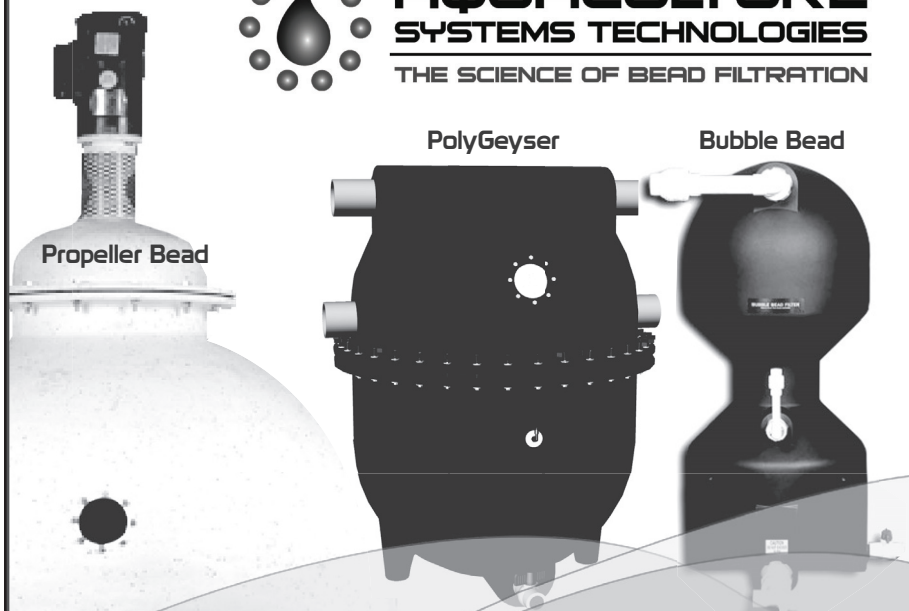
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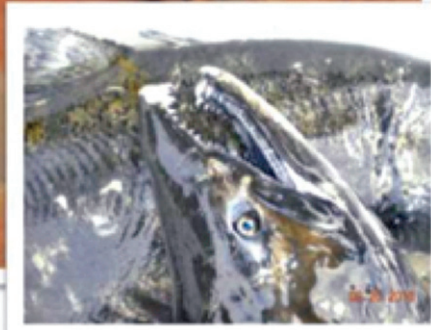
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Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture



FCS WORKING GROUP ON AQUACULTURE DRUGS, CHEMICALS, AND BIOLOGICS

Recommendations from the updated 2014 aquaculture drug guide

- This guide is intended for informational and educational use only.
- It is the responsibility of individuals administering regulated products to read and follow label instructions and be aware of any changes in relevant regulation prior to using these products.
- It is the responsibility of those using, prescribing, and/or recommending the use of regulated products to know which products can be legally used and with what restrictions under federal, state, and any other local regulations. Regulated product uses may vary by location, species, life stage, and culture conditions and methods.
- Remember, any use of an approved drug in a manner not specifically noted on the drug's label is illegal unless used where permitted under an Investigational New Animal Drug or under an extra-label prescription by a licensed veterinary.
- Remember that vaccination is just one component of a complete fish health program and cannot prevent all fish health problems. Seek professional advice regarding appropriate vaccine use before application.
- Certain active ingredients may be found in products labeled for aquatic and non-aquatic uses. Although the active ingredient may be the same, it is not legal to use a pesticide product in aquaculture unless it is labeled for such use.
- It is the responsibility of the user to understand the risks associated with using aquatic pesticides and herbicides and to know and comply with all relevant regulations governing their use in aquaculture. Use only pesticide and herbicide products that are labeled for use in aquaculture and follow all label instructions and safety precautions. And,
- Always read and understand the product literature before using any regulated product. When in doubt, seek professional advice. /ffn/

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Fish Health

Continued from previous page
common application methods.

The disinfectant section describes the most common uses for disinfectants in aquaculture, as well as appropriate compounds and application rates for aquaculture facilities.

The pesticide section focuses on the most common pesticide applications in aquaculture, including herbicides, algicides, and toxicants to fish and invertebrates.

Finally, the biologics section goes over the vaccines that are currently available for use in aquaculture. It also provides recommendations for their usage.

Biologics differ from drugs in a few ways. They affect the fish's immune system while drugs affect the disease-causing agent. Biologics are applied as a preventative – before infection – while therapeutics are applied post-infection. Also, most biologics leave no chemical residues in animals.

Authority

Several federal and state agencies are involved in regulating drugs, biologics, and other chemicals used in aquaculture. Each federal agency has specific, congressionally mandated responsibilities to regulate the products under their jurisdictions. In the case of aquaculture, there is some overlap between these federal agencies, as well as with state and local bodies.

The US Food and Drug Administration (FDA) regulates the manufacture, distribution, and use of new animal drugs and animal feed to ensure their safety and efficacy.

With respect to aquaculture, the US Environmental Protection Agency (EPA) has jurisdiction over disinfectants, sanitizers, and aquatic treatments used solely for the control of algae, bacterial slime, or pest control, excluding pathogens in or on fish. The EPA also administers the

National Pollutant Discharge Elimination System, which prohibits the discharge of pollutants, including regulated products, into waters of the US.

The Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture regulates all veterinary biologics, including vaccines, bacterins, antisera (blood serums), diagnostic kits, and other products of biological origin. APHIS ensures that pure, safe, potent, and effective veterinary biologics are available for the diagnosis, prevention, and treatment of animal diseases.

State agencies also may regulate the use of drugs, biologics, and other chemicals in aquaculture. Some states impose additional requirements and restrictions beyond those in the federal regulations.

Tables

The guide has several valuable tables. The first lists drugs currently approved or conditionally approved by the FDA for use in aquatic species. For more information about specific approved and conditionally approved drugs, there are individual drug links in Table 1.

The compounds described in Table 2 are considered to be of low regulatory priority when used for the indications listed. FDA has stated that it is unlikely to regulate the use of LRP drugs if the following five conditions are met:

- The substances are used for the listed indications;
- The substances are used at the prescribed levels;
- The substances are used according to good management practices;
- The product is of an appropriate grade for use in food animals; and
- There is not likely to be an adverse effect on the environment.

FDA permits the purchase, interstate shipment, and use of unapproved animal

Latest drug-use advice the result of extensive teamwork

Many thanks go to those who contributed to the 2014 update of the Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture. They include:

- Jim Bowker, US Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership Program, co-chair, Working Group on Aquaculture Drugs, Chemicals, and Biologics;
- Jesse Trushenski, Southern Illinois University Carbondale, Center for Fisheries, Aquaculture, and Aquatic Sciences, co-chair, Working Group on Aquaculture Drugs, Chemicals, and Biologics;
- Maren Tuttle-Lau, US Geological Survey, Upper Midwest Environmental Sciences Center;
- Dave Straus, US Department of Agriculture, Agricultural Research Service, Stuttgart National Aquaculture Research Center;
- Mark Gaikowski, US Geological Survey, Upper Midwest Environmental Sciences Center, co-chair, Working Group on Aquaculture Drugs, Chemicals, and Biologics;
- Andrew Goodwin, University of Arkansas Pine Bluff, Aquaculture and Fisheries Center;
- Laura Sprague, US Fish and Wildlife Service, Idaho Fish Health Center; and
- Molly Bowman, US Fish and Wildlife Service, Aquatic Animal Drug Approval Partnership Program. */ffn/*

drugs for investigational purposes through INAD exemptions. More detailed information about these compounds and what they can be used for are found in the fact sheet links of Table 3.

Get your guide

The new 2014 update of the guide was developed as a comprehensive introduction to the use of regulated products in aquaculture and as a resource for fisheries professionals. You can download a copy of the guide by visiting this shortened website address: <<http://tinyurl.com/kwypcj>>.

The guide is revised periodically to ensure that the information is accurate and current. Revisions include: new drug approvals and licensed vaccines;

new claims for existing drug approvals; and information on INADs.

In addition, revisions may include comments or suggestions provided by users of the guide. Please send feedback to Jesse Trushenski at <saluski@siu.edu> or Jim Bowker at <jim_bowker@fws.gov>.

Don't let the number of pages in the guide scare you off. It includes valuable information that is not easily found elsewhere. I was impressed with the thorough discussion of what some would consider cumbersome issues. I encourage you to give the guide a try.

Thanks for reading Fish Health Notes.

Dr. Rod Getchell works in the Aquatic Animal Health Program at the Cornell University College of Veterinary Medicine.



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